Using PDF and SAS Transport for Electronic Submissions

Greg Brolund
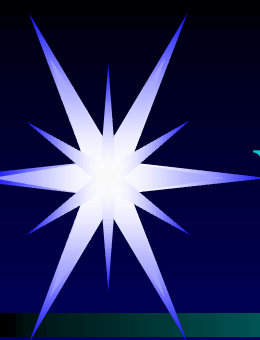
CDER / FDA

March 1, 1999
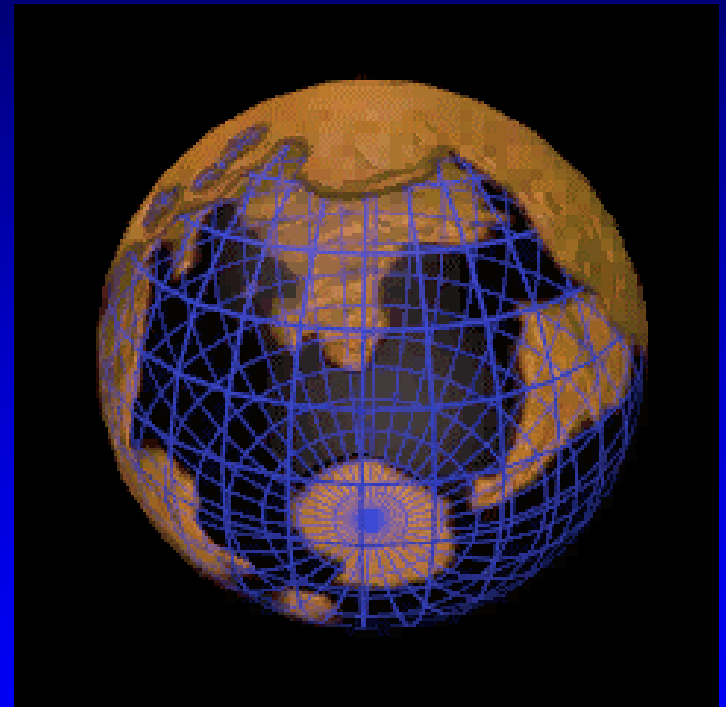
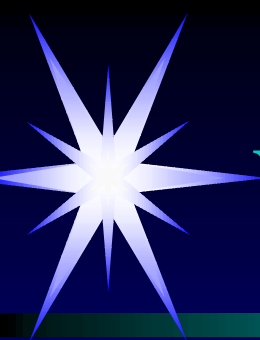# Overview

➤ Why PDF for text

➤ General PDF recommendations

➤ SAS Transport for datasets

➤ General SAS Transport recommendations
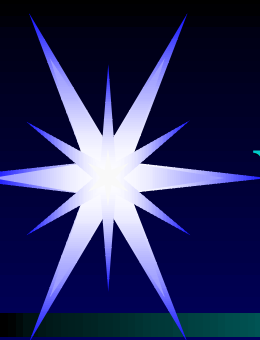
Why PDF? - General Requirements

➤ Archivable

➤ De facto standard

➤ Recommended ICH standard for text submission

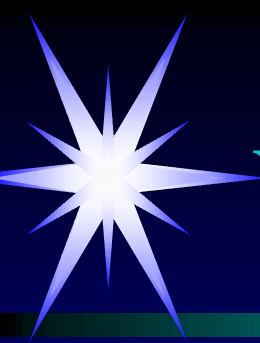➤ Company commitment to product and future readability

Why PDF? - FDA Requirements

➤ The electronic submission must maintain page fidelity

➤ Document sections must be able to be printed and appear as they would have on a paper submission in terms of font, page orientation, table formatting and page numbering.
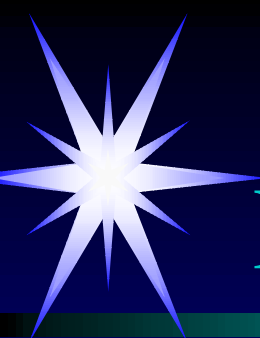
Why PDF? - FDA Requirements

➤ Replace paper, i.e. electronic copy must be trustworthy, complete and accurate.

➤ Allow efficient accessing, handling, review, and maintenance.

➤ Provide the ability to easily navigate through the submission.

Why PDF? - FDA Requirements

➤ Electronic submission must be able to be annotated and printed.

➤ Each submission, amendment and supplement must have a table of contents.

PDF Advantages

➤ Relatively low cost yet functional in terms of implementation and support.

➤ Free viewer

➤ Creation using a PDF device driver or from any Postscript file

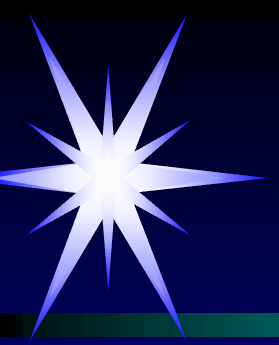➤ Detailed advance technical agreements are not necessary

PDF Advantages

➤ Functional navigational aids

➤ International support

➤ Multiple source (Word processor, HTML, SGML, TIFF, others)
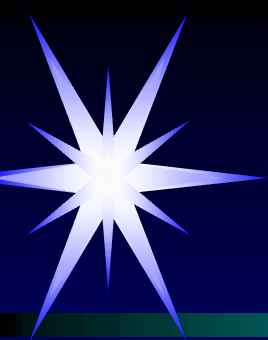
General PDF Recommendations

Fonts

➤ Limit the number of fonts used

➤ True Type or Adobe Type 1

➤ Embed all fonts
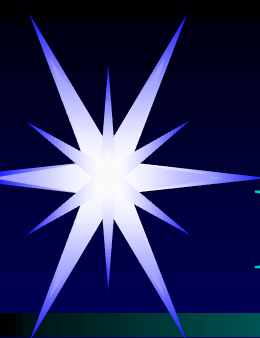
➤ Do not subset

Page Setup

➤ Present correct orientation

➤ Page Size 8 1/2 by 11

➤ Margins to allow binding

Original Documents

➤ Use electronic document as the source whenever possible

➤ Acrobat Distiller recommended

➤ Legibility is the primary consideration - select appropriate scanning resolution

➤ Black and white, if possible, to minimize size

Hyperlinks and Bookmarks

➤ In general:

    ➤ Bookmarks as a table of contents

    ➤ Hyperlinks for off page references

➤ See specific subsections for recommendations

➤ Select "Inherit Zoom" when creating links

Document Information Fields

➤ Provide index to make the fields searchable

➤ Use title field for requested information

➤ See guidance for specific information for each NDA item

General Info

D:\ichm2\Acknowledgment message\whitep13.pdf

Title: N123456, package insert, approved, 10jan1

Subject:

Author:

Keywords:

Creator: PSCRIPT.DRV Version 4.0

Producer: Acrobat Distiller 3.01 for Windows

Created: 4/17/98 8:50:11 AM

Modified: 4/17/98 8:50:11 AM

Optimized: No   File Size (Bytes): 77175

[OK]   [Cancel]

Document Security

➤ Do not restrict access

Document Security   ☒

Security Method:	None
Open Password:	No
Security Password:	No
Printing:	Allowed
Changing the Document:	Allowed
Selecting Text and Graphics:	Allowed
Adding or Changing Notes and Form Fields:	Allowed

[OK]

Indexing

➤ Acrobat Catalog

➤ Subdirectory for indexes

➤ See subsections for additional recommendations

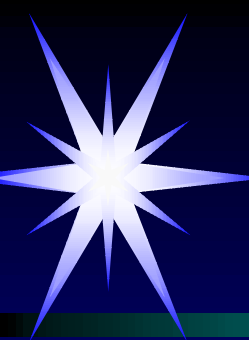➤ Link and automatically open the index

SAS Transport for Datasets

➤ Open specification

    ➤ www.sas.com/techsup/download/technote/ts140.txt

➤ Compatible with commonly used spreadsheet and statistical software

➤ Can be transferred to common database systems

➤ Easy to use in CDER and in many companies

➤ Third part software to build and read SAS Transport files

SAS Transport Recommendations

- ➤ SAS Transport Version 5
- ➤ Provide data definitions as PDF documents
  - ➤ Provide descriptive information in the transport description field
- ➤ Submit example data prior to filing
- ➤ Guidance has specific recommendations for each appropriate NDA items
- ➤ 25 Mbytes / file or less

Final Guidance Jan 27, 1999!